REMARKS

Claims 1-6, 35, 36, 38, and 39 are pending in the application. The status of canceled claims 7-34 and 37 has been corrected in the above-identified listing of claims as requested by the examiner.

Rejections under 35 U.S.C. § 103(a)

1. Claims 1-4, 35, 36, and 38 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over two combinations of references: McGuire (5562669) in view of Dumican et al. (4987665) and Roger et al (6235057), and McGuire in view of Li et al. (5715942) and Roger et al. In view of the following arguments, Applicants respectfully traverse these rejections.

The examiner states that the McGuire reference discloses each of the following elements: allografts used as replacement ligaments, sutures attached to both proximal and distal ends of the ligament, the use of semitendinosis and gracilis tendons, sutures attached prior to implantation to aid in insertion, grafts preserved for future ligament replacement procedures, grafts that can be a bundle of strands, and fixation devices used in "kits" for ligament repair. The examiner states that because the individual components of the applicant's claimed kit for ligaments are known in the art, it can be construed that any type of combination of these components available at the same time form a "kit". What is deficient in the McGuire reference, the examiner states, is that it does not disclose a package or kit with sutures attached to the graft (lacking bone plugs) prior to sterilizing and packaging. Both Dumican and Li allegedly disclose medical devices with sutures or suture materials pre-packaged and sterilized prior to use in surgery. The teaching that the examiner is relying upon in the secondary Dumican and Li references is that all elements of the devices are packaged together prior to sterilization. Finally, the examiner relies on Roger et al for the teaching that bone blocks are not necessary with grafts made from tendons with sutures at the ends (col. 2, lines 28-31).

The present invention is a package for use in ligament replacement surgery wherein the graft material is non-autologous, pre-attached with sutures on both proximal and distal ends, and lacking bone plugs. Applicants respectfully submit that McGuire as modified by either Dumican or Li and Roger does not describe grafts that lack bone plugs. Roger et al is cited by the examiner for allegedly teaching that bone blocks are not necessary with grafts made from tendons with sutures at the ends (col. 2, lines 28-31). Applicants respectfully submit that there is no suggestion or motivation in Roger to make a pre-packaged, sterile tendon graft with sutures at the ends and lacking bone plugs.

Roger et al is directed to a method for the reconstruction of the anterior cruciate ligament comprising forming a tendon graft, forming holes through the patient's femur and tibia, drawing the tendon graft through the holes, and securing both ends of the graft to the patient's femur and tibia with a suitable screw, peg, or other fixation device having a leading end and a trailing end (cols. 2-4). The tendon graft is derived from the hamstring tendon of the patient or from the achilles tendons of cadavers (col. 2, lines 34-37). Col. 2, lines 28-32 read:

> It has been surprisingly found that, even without the presence of a bone block, a screw or other similar fixation device can adequately secure the tendon graft in place in both the femoral hole and the tibial hole.

Applicants respectfully submit that the disclosure of Roger cited by the examiner is directed to the discovery that tendon grafts can be harvested *in situ* from the patient without the need to harvest or attach bone block portions on either end of the tendon graft and not related to pre-packaged bone grafts. As Roger describes in the background section, the prior art methods for reconstruction of the anterior cruciate ligament included attempts to connect harvested tendons to the femur and tibia by staples, screws, or the like inserted exteriorly to the bone (col. 1, lines 27-34); the use of bone-tendon-bone grafts harvested from the patient and secured in the femur and tibia by a screw driven between the wall of the hole drilled into the bone and the bone block (col. 1, lines 44-49); and the use of hamstring tendon sutured to a bone block (col. 1, lines 53-57). Roger describes that the harvested tendon can be secured to the patient's bone without the need to also harvest bone blocks or to attach bone blocks to the harvested tendon. The

tendon graft can be drawn through the holes drilled into the femur and tibia and secured in place at either end with a screw or other fixation device.

As disclosed by Applicants in the instant specification, the use of packaged and sterile replacement ligaments provided without bone plugs is particularly useful, for example with fixation techniques which do not use bone plugs, for instance in surgical situations wherein a crosspin is used to capture a looped replacement ligament (US Application 2002/0165611, paragraph 8). Roger does not disclose packaged tendons with sutures lacking bone plugs available for use in fixation techniques which do not use bone plugs. Roger merely teaches that tendon grafts may be secured in the patient with screws or pegs, in the absence of bone blocks.

Roger does not describe pre-packaged grafts lacking bone plugs. Instead, Roger describes harvesting a tendon *in situ* during ligament reconstruction surgery. Applicants respectfully disagree with the examiner that Roger is relevant to packaged bone grafts lacking bone plugs. Nevertheless, Applicants have amended independent claims 1 and 35 to recite a replacement package comprising pre-packaged grafts.

Further, there must be some motivation or suggestion found either explicitly or implicitly in the cited references to modify the reference or to combine reference teachings. The examiner has not provided his basis in the references for opining that it would have been obvious to one of skill in the art to combine the McGuire, Roger, and Dumican or Li references to have pre-attached sutures on the graft ligament of McGuire and have the sutures already attached prior to packaging and sterilizing as taught by Dumican or Li and not use a block as taught by Roger.

In view of the foregoing, Applicants submit that claims 1 and 35, and claims 2-4, 36, and 38 dependent therefrom, are not rendered obvious by McGuire in view of Dumican or in view of Li and further in view of Roger. McGuire does not disclose grafts that lack bone plugs. Dumican, Li, and Roger do not cure this deficiency. In order to support a proper 103(a) rejection, the cited reference or combination of references must teach or suggest all limitations of the Applicants' claims and there must be some suggestion or motivation to combine the references.

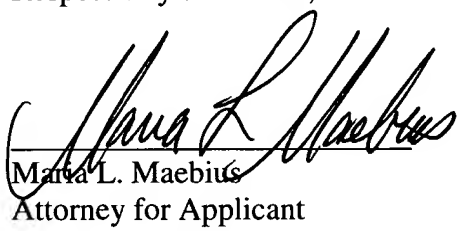
2. Claims 5, 6, and 39 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over two combinations of references: McGuire (5562669) in view of Dumican et al. (4987665) and Roger (6235057) and further in view of Schmieding (5415651), and McGuire in view of Li et al. (5715942) and Roger (6235057) and further in view of Schmieding (5415651). The examiner's argument is that it would have been obvious to one of ordinary skill in the art to use the teachings of Schmeiding for long sutures and various lengths of ligaments for the graft of McGuire as modified by either Dumican or Li and Roger in order to provide the proper length of ligament replacement necessary for the patient and to have sufficient suture to secure it in place. In view of the foregoing arguments regarding claims 1-4, 35, 36, and 38, this rejection is respectfully traversed.

Applicants submit that claims 5, 6, and 39 are not rendered obvious by McGuire in view of Dumican and Roger and further in view of Schmieding, or in view of Li and Roger and further in view of Schmieding. McGuire as modified by either Dumican or Li and Roger does not disclose graft material for ligament replacement procedures wherein the material lacks bone plugs. Schmeiding does not cure this deficiency. In order to support a proper 103(a) rejection, the cited reference or combination of references must teach or suggest all limitations of the Applicants' claims and there must be some suggestion or motivation to combine the references.

CONCLUSION

In view of the foregoing remarks, Applicants believe that the application is in condition for allowance. However, if the Examiner disagrees, he is encouraged to call the undersigned at the number listed below in order to expedite the prosecution of this application.

Respectfully submitted,



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